NHS GRAMPIAN
Minute of Formulary Group Meeting
Tuesday 20 September 2022 at 14:30 via Microsoft Teams

PRESENT	APOLOGIES	APPROVED
Ms L Cameron	Ms A Davie	
Dr V Chieng	Mrs L Montgomery	
Dr D Culligan	Dr J Newmark	
Ms F Doney (Vice-Chair)	Mr R Sivewright	
Dr E Elias		
Dr L Elliot (Chair)		
Ms M Galvin		
Mrs G McKerron		
Dr M Metcalfe (Vice-Chair)		
Mrs K Neave		
Mrs S O'Beirne		
Mr M Paterson		

ITEM	SUBJECT	ACTION

The Chair welcomed members, opened the meeting and noted that a quorum was present.

1. APOLOGIES

Apologies for absence were requested and noted.

2. DRAFT MINUTE OF THE MEETING HELD 16 AUGUST 2022

The Group accepted the draft note of the meeting subject to minor typographical changes.

The corrected final approved minute will be in the public domain within 21 days of approval. **FD**

3. PRESENTATION - NONE

4. MATTERS ARISING

4.1. Action Log

The action log was noted.
No additional items were identified that should have been included on the agenda.

4.2. Pentosan (Elmiron®)

Ms Doney reported that the requestor has been in contact to advise that the Medicines and Healthcare products Regulatory Agency (MHRA) has amended its 2019 Drug Safety Update article '*Elmiron (pentosan polysulfate sodium): rare risk of pigmentary maculopathy'* to make the recommendations for eye tests clearer. The previous advice, 'at baseline and annually', has been replaced by the latest guidance in the Summary of Product Characteristics (SmPC).

It was noted that Consilient Health, the Marketing Authorisation Holder (MAH) for Elmiron®, does not host its Summary of Product Characteristics (SmPCs) on the electronic medicines compendium (emc). However, the Formulary Team will ensure there is a link to the SmPC on the formulary website. **FTEAM**

ITEM	SUBJECT	ACTION

5. FORMULARY GROUP DECISIONS AUGUST 2022 - PUBLISHED - 29/08/2022

Members ratified the decisions of the August 2022 meeting as published. **FTEAM**

6. NETFORMULARY/FORMULARY REVIEW

6.1. SMC 2439 - Solriamfetol (Sunosi®)

Dr Culligan declared a personal, non-specific interest in Jazz Pharmaceuticals UK Limited and took part in decision-making.

Dr Elliot confirmed that:
- July 2022 [following a full submission assessed under the orphan equivalent process] SMC issued a positive recommendation for solriamfetol (Sunosi®) to improve wakefulness and reduce excessive daytime sleepiness in adults with narcolepsy (with or without cataplexy), SMC 2439
- the Neurology Service does not wish to apply for formulary inclusion for solriamfetol, for this indication, as there is not a local need at this time

The Group accepted the position presented by the Neurology Service and ratified the request that solriamfetol should be categorised as 'non-formulary - not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time'.

SMC 2439 - Solriamfetol 150mg film-coated tablets (Sunosi®) ▼ is not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time.
Indication under review: to improve wakefulness and reduce excessive daytime sleepiness in adult patients with narcolepsy (with or without cataplexy).
SMC restriction: for use in patients who have failed modafinil or have a contraindication or intolerance to modafinil.
Solriamfetol, compared with placebo, reduced excessive daytime sleepiness in adults with narcolepsy.
This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.
Not routinely available as local clinical experts do not wish to add the medicine to the formulary at this time. **FTEAM**

6.2. Discontinuation of paroxetine 20mg/mL liquid

Dr Culligan declared a personal, non-specific interest in GlaxoSmithKline (GSK) UK Ltd.

Dr Elliot confirmed that:
- for commercial reasons GSK has taken the decision to discontinue Seroxat® 20mg/10mL oral suspension from the UK and other markets in October 2022
- there is not currently an alternative licensed liquid formulation of paroxetine and it is unclear if the lack of an oral liquid will make titrating patients off paroxetine treatment more difficult

Paroxetine 20mg/10mL oral suspension (Seroxat®) is now withdrawn from use/discontinued.
Indications under review: for the treatment of:
- **Major Depressive Episode**
- **Obsessive Compulsive Disorder**
- **Panic Disorder with and without agoraphobia**
- **Social Anxiety Disorders/Social phobia**
- **Generalised Anxiety Disorder**
- **Post-Traumatic Stress Disorder**

This medicine is now withdrawn from use/discontinued. **FTEAM**

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6.3. Abiraterone (Zytiga®) patent loss

Ms Galvin confirmed that:

- abiraterone, as the brand Zytiga®, has recently lost its patent and generic products are expected
- there is a significant spend on abiraterone for prostate cancer
- currently the supply arrangements for abiraterone are via Community Pharmacies (via hospital-based prescription). However, this is unlikely to be viable with the availability of generic abiraterone products.
- dispensing/supply may move to the managed service or by a homecare arrangement, and the plan will be clearer next month

An update will be available for the October meeting. **MG**

6.4. Blood Glucose test strips for Type 2 Diabetes

The Group considered the document outlining the Diabetic Managed Clinical Network (MCN) updated choice of meters and strips for the self-monitoring of blood glucose (SMBG) for Type 2 diabetes.

Ms Doney confirmed that the Diabetic MCN is responsible for development, implementation and dissemination of the recommendations and the request of the Formulary Group is to ratify the recommendations [as one step in the implementation process].

The Group supported the Diabetic MCN recommendations for the SMBG for Type 2 diabetes, and ratified the updated choices for hosting on the formulary. **FTEAM**

6.5. Formulary traffic light review

Ms Doney reported that the Formulary Team is undertaking a review of the current formulary classification and traffic light system, primarily to ensure that items in the Pharmacy First Approved List are easier to identify.

A proposal will be presented at the October meeting, **FTEAM**

7. OTHER BUSINESS

7.1. NHS Scotland climate emergency sustainability strategy 2022 - 2026

Dr Elliot highlighted the 'NHS Scotland climate emergency sustainability strategy 2022 - 2026', confirming that this is something the Group will need to consider in its decision-making.
The Respiratory MCN is aware of and considering the strategy in relation to the current inhaler choices.

Ms Doney confirmed that as this will be an ongoing piece of work the strategy document will be posted on the Formulary Group Teams™ site. **FTEAM**

8. NEW PRODUCT REQUESTS

8.1. FG1SMC 2467 - Filgotinib (ulcerative colitis)

There were no declarations of interest recorded in relation to this product.

The Group considered the request for filgotinib for the treatment of adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent.

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The Group noted that:

- filgotinib is already included on the formulary for severe active rheumatoid arthritis
- the global prevalence of UC is increasing, and UC is an immune-mediated disease characterised by chronic inflammation of the colon. A therapeutic goal is the induction and maintenance of remission.
- evidence for filgotinib in UC comes from the SELECTION programme. SELECTION included two induction studies (UC-1 and UC-2) followed by a maintenance study (UC-3), with a total duration of 58 weeks of therapy which is a short timescale for a long-term treatment.
  - in the induction studies filgotinib 200mg demonstrated a statistically significant higher proportion of patients achieving clinical remission in both biologic-naïve and experienced treatment arms at Week 10 compared to placebo. Despite 43.1% of patients in induction study B having previous failure of both tumour necrosis factor (TNF)-alpha inhibitor or vedolizumab treatment.
  - in the maintenance study, filgotinib 200mg achieved the primary endpoint of statistically significantly greater rates of remission compared to placebo. In addition, a significantly greater proportion of patients given filgotinib 200mg than placebo had 6-month corticosteroid-free remission at week 58.
- filgotinib is a Janus kinase (JAK) inhibitor that preferentially inhibits JAK1 over JAK2, JAK3, and tyrosine kinase 2, and this might confer an improved safety profile
- the European Medicines Agency (EMA) is currently conducting a safety review of the JAK inhibitors used to treat several chronic inflammatory disorders (rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis) and was updated June 2022 to include ulcerative colitis, alopecia areata, and non-radiographic axial spondyloarthritis, https://www.ema.europa.eu/en/medicines/human/referrals/janus-kinase-inhibitors-jaki]
- the SMC advice takes account of the benefits of a PAS that improves the cost-effectiveness of filgotinib
- costs will be cumulative as filgotinib is potentially a long-term treatment, and some costs are already in the system as alternative lines of therapy are available for this patient group
- filgotinib is licensed for UC induction and maintenance of remission, although data for remission is limited, inclusion on the formulary would provide an alternative oral JAK inhibitor [to tofacitinib] with a simple once-a-day dosing regimen
- use in clinical practice will confirm the place of filgotinib in the current UC treatment pathway, but alternative agents are required where TNF-alpha inhibitors are not appropriate

Members discussed the risk of hyperlipidaemia with the JAK inhibitors and emphasised the need for cardiovascular risk assessments, particularly in the chronic inflammatory conditions and in view of the current EMA safety review.

The Group accepted the restricted local need for filgotinib, as an additional JAK inhibitor, for the treatment of adults with moderately to severely active UC, as outlined in SMC 2467.

SMC 2467 - Filgotinib 100mg, 200mg film-coated tablets (Jyseleca®) ▼ is routinely available in line with national guidance (SMC 2467).
Indication under review: for the treatment of adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent. Filgotinib provides an additional treatment choice in the therapeutic class of janus kinase (JAK) inhibitors.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. It was classified 1b - available for restricted use under specialist supervision and 8b -

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	recommended for hospital use only. Treatment should be initiated by a physician experienced in the treatment of ulcerative colitis.	**FTEAM**

Items 8.2 and 8.3 were taken together.

8.2. FG1SMC 2417 - Upadacitinib (atopic dermatitis) and

8.3. FG1SMC 2431 - Abrocitinib (atopic dermatitis)

Dr Culligan declared a personal, non-specific interest in AbbVie Ltd and took part in decision-making.

The Group considered the requests for two JAK inhibitors, upadacitinib and abrocitinib, for the treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years and older who have had an inadequate response to at least one conventional systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable.

The Group noted that:

- in the SMC advice the Marketing Authorisation Holders (MAHs) positioned their JAK inhibitors for use in a sub-group of their atopic dermatitis licences – '*in those who have not responded to, or have lost response to, at least one systemic immunosuppressant therapy, or in whom these are contraindicated or not tolerated'*
- upadacitinib preferentially inhibits signalling by JAK1 or JAK1/3 with functional selectivity over cytokine receptors that signal via pairs of JAK2
- abrocitinib has selectivity for JAK1 over the other three JAK isoforms JAK2 (28-fold), JAK3 (> 340-fold) and tyrosine kinase 2 (TYK2, 43-fold)
- atopic dermatitis is driven by pro-inflammatory cytokines that transduce signals via the JAK1 pathway. Inhibiting JAK1 reduces the signalling of many mediators which drive the signs and symptoms of atopic dermatitis such as eczematous skin lesions and pruritus.
- NICE TA814 [abrocitinib, tralokinumab and upadacitinib] confirmed that for all people who had treatment in the key clinical evidence studies the results showed a greater chance of reaching a 50% reduction in Eczema Area and Severity Index (EASI) score (EASI 50) plus an improvement of at least 4 in the Dermatology Life Quality Index (DLQI) score at week 12 or 16, than people who had a placebo. These results were statistically significant for abrocitinib and upadacitinib.
- the marketing authorisations for abrocitinib and upadacitinib include young people aged 12 to <18 years with atopic dermatitis. NICE considered that the current treatment pathways for adults and young people with atopic dermatitis are similar. However, the paediatric patient numbers in the studies were small.
- the EMA is currently conducting a safety review of the JAK inhibitors used to treat several chronic inflammatory disorders
- cost-effectiveness is based on cost-minimisation versus dupilumab with the assumption that the agents are at least similar to dupilumab in terms of people responding to treatment
- costs are already in the system from the use of monoclonal antibodies and baricitinib
- upadacitinib and abrocitinib are expected to be supplied by a homecare arrangement
- the SMC advice takes account of the benefits of PASs that improve the cost-effectiveness of upadacitinib and abrocitinib
- baricitinib is already included on the formulary for atopic dermatitis, however it is not licensed for adolescents
- upadacitinib and abrocitinib have low-dose and high-dose treatment options

The Group accepted the restricted local need for the JAK inhibitors, upadacitinib and abrocitinib, for the treatment of moderate-to-severe atopic dermatitis, as outlined in SMC 2417 and SMC 2431 respectively.

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SMC 2417 - Upadacitinib 15mg, 30mg prolonged-release tablets (Rinvoq®) ▼ is routinely available in line with national guidance (SMC 2417).
Indication under review: for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who have had an inadequate response to at least one conventional systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable.
In patients with moderate to severe atopic dermatitis eligible for systemic therapy, upadacitinib was associated with significantly greater improvements in the signs and symptoms of atopic dermatitis in adults and adolescent patients in three placebo-controlled phase III studies and in adult patients in one phase III comparative study with a monoclonal antibody.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and supervised by a healthcare professional experienced in the diagnosis and treatment of atopic dermatitis. **FTEAM**

SMC 2431 - Abrocitinib 50mg, 100mg, 200mg film-coated tablets (Cibinqo®) ▼ is routinely available in line with national guidance (SMC 2431).
Indication under review: for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who have had an inadequate response to at least one conventional systemic immunosuppressant such as ciclosporin, or in whom such treatment is considered unsuitable.
Four phase III studies demonstrated superiority of abrocitinib in improving signs and symptoms of atopic dermatitis when compared with placebo, as monotherapy or in combination with medicated topical therapies in patients with moderate to severe atopic dermatitis.
This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and supervised by a healthcare professional experienced in the diagnosis and treatment of atopic dermatitis. **FTEAM**

8.4. FG1SMC 2462 - Fedratinib (myelofibrosis)

Dr Culligan declared a personal, non-specific interest in Bristol Myers Squibb Pharmaceuticals Limited and took part in decision-making.

The Group considered the request for the JAK inhibitor, fedratinib, for the treatment of disease-related splenomegaly or symptoms in adults with primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis who are JAK inhibitor naïve or have been treated with ruxolitinib (SMC 2462).

The Group noted that:
- myelofibrosis is a rare haematological disorder that shortens life, often causes an enlarged spleen and constitutional symptoms with a high symptom burden
- fedratinib was accepted for use in NHS Scotland following an abbreviated submission reviewed by the SMC executive
- ruxolitinib, another JAK inhibitor licensed for use in this population and accepted for use in NHS Scotland, was assessed under the orphan equivalent process and subject to a Patient and Clinician Engagement (PACE) meeting
- fedratinib is a JAK2-selective inhibitor with higher inhibitory activity for JAK2 over JAK1, JAK3 and TYK2

- local specialist are positioning fedratinib for use after ruxolitinib, due to its less favourable adverse effect profile
- evidence (for this population) comes from JAKARTA-2 (n=97), an open-label, non-randomised, phase II study in adults with intermediate or high-risk primary myelofibrosis, post-polycythaemia vera myelofibrosis, or post-essential thrombocythaemia myelofibrosis that was deemed resistant to ruxolitinib
- JAKARTA-2:
  - was terminated early due to cases of serious and fatal encephalopathy, including Wernicke's
  - primary efficacy endpoint was the proportion of patients achieving a ≥35% reduction in spleen volume from baseline to the end of cycle 6
  - in the intentional to treat population (n = 97, versus 83 that completed 6 cycles before the study was terminated) the percentage of patients (95% confidence interval) who achieved a ≥35% reduction in spleen volume by MRI or CT at the 400mg dose at the end of cycle 6 was 22.7% (22/97, 95% CI: 14.8%, 32.3%)
- treatment may be continued for as long as patients derive clinical benefit, however as the studies were stopped early it is unclear how long patients might remain on treatment
- there is a potential that patients who are refractory to fedratinib might remain on treatment if it was offering some benefit (without significant toxicity)
- fedratinib requires thiamine level monitoring, and the Biochemistry Service can improve the turnaround time for patients on fedratinib
- life expectancy for people who stop ruxolitinib is around 12 to 18 months; most people in JAKARTA-2 had died within 2 to 3 years of stopping fedratinib, even though most had retreatment with ruxolitinib; the median overall survival after stopping ruxolitinib was 16 months or less in COMFORT-2
- there are gaps in the data - absence of direct head-to-head evidence comparing the efficacy of fedratinib with best available therapy, or against ruxolitinib continued with sub-optimal response; no overall survival (OS) data but evidence of spleen response; small sample size and short follow up
- myelofibrosis can transform into Acute Myeloid Leukaemia (AML) and it is unclear whether fedratinib treatment affects AML transformation
- fedratinib would be another oral treatment option that in patients that respond to treatment, has the potential to improve quality of life (reduce symptoms) including those that have previously had ruxolitinib

Dr Culligan confirmed the significant symptom burden that people with myelofibrosis have to endure, that there are few effective treatments and bone marrow transplant is an option for very few patients. Reducing symptoms (itch, sweating) and improving appetite are more important for patients than reducing spleen volume.

The Group accepted the restricted local need for fedratinib as requested by the Haematology Service used after ruxolitinib for the treatment of disease-related splenomegaly or symptoms in adults with primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.

SMC 2462 - Fedratinib 100mg hard capsules (Inrebic®) ▼ is routinely available in line with national guidance (SMC 2462).
Indication under review: for the treatment of disease-related splenomegaly or symptoms in adults with primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis who are Janus Associated Kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.
Fedratinib provides an additional treatment choice in the therapeutic class of JAK inhibitors.
Another medicine within this therapeutic class has been accepted via the orphan medicine process.

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	This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment with fedratinib should be initiated and monitored under the supervision of physicians experienced in the use of anti-cancer medicinal products.	FTEAM

8.5. FG1SMC 2427 - Venetoclax (chronic lymphocytic leukaemia)

Dr Culligan declared a personal, specific interest in AbbVie Ltd for venetoclax in the management of AML, and took part in decision-making.

The Group considered the request for venetoclax used in combination with obinutuzumab for the treatment of adults with previously untreated chronic lymphocytic leukaemia (CLL).

The Group noted that:

- venetoclax:
  - is an inhibitor of B-cell lymphoma-2 (BCL-2), it has demonstrated cytotoxic activity in tumour cells that overexpress BCL-2. By attaching to BCL-2 and blocking its actions, venetoclax causes the death of cancer cells and thereby slows down progression of the disease.
  - meets SMC orphan equivalent criteria in this indication
  - [for this indication] was accepted for restricted use within NHS Scotland in combination with obinutuzumab for the treatment of adults with previously untreated CLL in patients without del (17p)/TP53 mutation who are fit to receive fludarabine, cyclophosphamide and rituximab (FCR) chemo-immunotherapy
  - is already included on formulary [in combination with obinutuzumab] for the treatment of adults with previously untreated CLL with or without del (17p)/TP53 mutation in those who are not fit to receive FCR chemo-immunotherapy (SMC 2293)
  - [for this indication] is given as a fixed-length treatment course of 12 cycles, with obinutuzumab given for the first six cycles
- evidence comes from interim results of CLL13. The primary outcomes are, progression-free survival (PFS) with results expected in 2023, and undetectable minimal residual disease (uMRD) in peripheral blood at 15 months. Data (cut-off 28/02/2021) indicated that the proportion of patients achieving uMRD in peripheral blood was significantly lower with standard chemo-immunotherapy (FCR or bendamustine-rituximab) compared with venetoclax-obinutuzumab and with venetoclax-obinutuzumab-ibrutinib (52% versus 87% and 92%).
- network meta-analyses suggested that venetoclax-obinutuzumab, compared with FCR, was likely associated with greater PFS and at least comparable OS
- there is a degree of cost-offset available from the displacement of FCR, and in patients with del (17p)/TP53 mutation venetoclax-obinutuzumab will be an alternative treatment option to the Bruton's tyrosine kinase (BTK) inhibitors, e.g., ibrutinib or acalabrutinib, as venetoclax-obinutuzumab will be used where BTK inhibitors are not chosen by the patient/clinician
- this SMC advice along with SMC 2293 would make venetoclax plus obinutuzumab a first-line treatment option in CLL for 1) those not fit for FCR chemo-immunotherapy regardless of del (17p)/TP53 mutation and 2) those fit for FCR chemo-immunotherapy with del (17p)/TP53 mutation

The Group accepted the restricted local need for venetoclax in combination with obinutuzumab, as outlined in SMC 2427.

ITEM	SUBJECT	ACTION
	SMC 2427 - Venetoclax 10mg, 50mg, 100mg film-coated tablets (Venclyxto®)▼ is routinely available in line with national guidance (SMC 2427). **Indication under review: in combination with obinutuzumab for the treatment of adults with previously untreated chronic lymphocytic leukaemia (CLL)** **Restriction: in patients without del (17p)/TP53 mutation who are fit to receive fludarabine, cyclophosphamide and rituximab (FCR) chemo-immunotherapy.** **Venetoclax in combination with obinutuzumab, compared with standard therapies, was associated with clinical benefits in patients who were fit and unfit to receive FCR chemo-immunotherapy.** **This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.** **For SMC advice relating to the use of venetoclax in (1) patients without del (17p)/TP53 mutation who are not fit to receive FCR chemo-immunotherapy and (2) patients with del (17p)/TP53 mutation, please refer to SMC 2293. It was classified 1b - available for restricted use under specialist supervision and 8b - recommended for hospital use only. Treatment should be initiated and supervised by a physician experienced in the use of anticancer medicinal products.**	**FTEAM**

9. SCOTTISH MEDICINES CONSORTIUM PROVISIONAL ADVICE - ISSUED SEPTEMBER 2022

The Group noted the SMC provisional advice issued September 2022.

If the negative SMC recommendation is published next month, this medicine will not be included on the formulary for the indication in question.

10. SCOTTISH MEDICINES CONSORTIUM PRESS STATEMENTS - PUBLISHED SEPTEMBER 2022

The Group noted the SMC advice published September 2022.

Following publication of the negative SMC recommendation, for zanubrutinib (Brukinsa®)▼ SMC 2452, this medicine will not be included on the Grampian Joint Formulary for the indication in question.

The following SMC accepted medicines have not been processed within a 60-day timescale:

- SMC 2502 Bijuve® (estradiol/micronised progesterone) (submission expected)
- SMC 2473 Sativex® (delta-9-tetrahydrocannabinol/cannabidiol) (submission expected)
- SMC 2441 trifarotene (Aklief®)▼ (clinicians not responded)
- SMC 2472 apalutamide (Erleada®)▼ (submission expected)
- SMC 2458 nivolumab (Opdivo®) (clinicians not responded)
- SMC 2445 imlifidase (Idefirix®)▼ (clinicians not responded)
- SMC 2463 tofacitinib (Xeljanz®) (clinicians not responded)

Local advice for these medicines and indications will be included in the September 2022 decisions as 'Not routinely available as the ADTC is waiting for further advice from local clinical experts'. **FTEAM**

UMAR SMC 2466 - VELMANASE ALFA (LAMZEDE®)

There were no declarations of interest recorded in relation to this product.

Members noted the content of the SMC ultra-orphan medicines assessment report (UMAR) and the summary document for velmanase alfa (Lamzede®).

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Ms Doney confirmed that:

- velmanase alfa has been validated as meeting SMC ultra-orphan (UO) criteria and will be made available through the NHS in Scotland for up to three years [for the indication in question] while evidence on its effectiveness is generated.
  After three years, the company will provide an updated submission to SMC for reassessment to allow a decision on its routine use in NHS Scotland to be made.
- UO medicines undergoing an initial assessment of evidence by the SMC are considered outwith remit for the Formulary Group

In line with local processes, the Group recorded velmanase alfa (Lamzede®) [SMC 2466] as not routinely available in NHS Grampian.

SMC 2466 - Velmanase alfa 10mg powder for solution for infusion (Lamzede®) ▼ is not routinely available in NHS Grampian.
Indication under review: enzyme replacement therapy for the treatment of non-neurological manifestations in patients with mild to moderate alpha-mannosidosis.
Not routinely available in NHS Grampian. If local need identified contact the Pharmacist Team Leader/Principal Pharmacist - Supply (ARI). FTEAM

11. GENERAL INFORMATION FROM SCOTTISH MEDICINES CONSORTIUM – SEPTEMBER 2022

None.

12. DOCUMENTS FOR INFORMATION

Items 12.1 (Drug Safety Update August 2022) and 12.2 (Antimicrobial Management Team (AMT) minute June 2022) were noted.

13. AOCB

None

DATE OF NEXT MEETING

Tuesday 18 October 2022 starting at 14.30 via Microsoft Teams

CHAIR'S SIGNATURE _____ **DATE 18 OCTOBER 2022**